DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 13, 2016

Globus Medical Incorporated
Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K143578
Trade/Device Name: SUSTAIN® R TPS Spacers, PATRIOT® TPS Spacers, CALIBER® TPS Spacer, COALITION® TPS Spacers, INDEPENDENCE® TPS Spacer, FORTIFY®-R TPS Corpectomy Spacer, FORTIFY® I-R TPS Corpectomy Spacer, XPand®-R TPS Corpectomy Spacer, NIKO® TPS Corpectomy Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, OVD, OVE, MQP
Dated: April 5, 2016
Received: April 6, 2016

Dear Dr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143578

Device Name
SUSTAIN® R TPS Spacers, PATRIOT® TPS Spacers, CALIBER® TPS Spacer, COALITION® TPS Spacers, INDEPENDENCE® TPS Spacer, FORTIFY®-R TPS Corpectomy Spacer, FORTIFY® I-R TPS Corpectomy Spacer, XPand®-R TPS Corpectomy Spacer, NIKO® TPS Corpectomy Spacer

Indications for Use *(Describe)*

SUSTAIN® Spacers

When used as lumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R and SUSTAIN® R TPS) are intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of nonoperative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). SUSTAIN® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE®, REVOLVE®, or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. SUSTAIN® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE®, or XTEND® Anterior Cervical Plate Systems.

When used as vertebral body replacement devices, SUSTAIN® Spacers are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with bone grafting material. SUSTAIN® Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

PATRIOT® Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Constitution® TPS, Signature®, Signature® TPS, Continental®, Continental® TPS, TransContinental®, TransContinental® TPS, TransContinental® M, and TransContinental® M TPS) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

PATRIOT® Cervical Spacers

PATRIOT® Spacers (including COLONIAL® and COLONIAL® TPS) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE® or PROVIDENCE® Anterior Cervical Plate Systems.

CALIBER® Spacers
CALIBER® Spacers (including CALIBER® TPS) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

CALIBER® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE® or REVOLVE® Stabilization Systems.

COALITION® Spacers
COALITION® Spacers (including COALITION® TPS) are stand-alone interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. COALITION® Spacers are to be filled with autogenous bone graft material, and are to be used with two titanium alloy screws which accompany the implants.

INDEPENDENCE® Spacers
INDEPENDENCE® Spacers (including INDEPENDENCE® TPS) are stand-alone interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). INDEPENDENCE® Spacers are to be filled with autogenous bone graft material, and are to be used with three titanium alloy screws, which accompany the implants.

FORTIFY® Corpectomy Spacers
FORTIFY® (including FORTIFY®-R and FORTIFY®-R TPS) and FORTIFY® Integrated (including FORTIFY® I-R and FORTIFY® I-R TPS) Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These devices are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with autogenous bone graft or allograft. These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

XPand® Corpectomy Spacers
XPand® Corpectomy Spacers (including XPand®-R and XPand®-R TPS) are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). XPand® Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate system, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. XPand® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

NIKO® Corpectomy Spacers
NIKO® Corpectomy Spacers (including NIKO® TPS) are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). NIKO® Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with bone grafting material. NIKO® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary: TPS Spacers

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: February 25, 2016

Device Name: SUSTAIN® R TPS Spacers
PATRIOT® TPS Spacers
CALIBER® TPS Spacer
COALITION® TPS Spacers
INDEPENDENCE® TPS Spacer
FORTIFY®-R TPS Corpectomy Spacer
FORTIFY® I-R TPS Corpectomy Spacer
XPand®-R TPS Corpectomy Spacer
NIKO® TPS Corpectomy Spacer

Classification: Per 21 CFR as follows:
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3080 Intervertebral Body Fusion Device
Product Code(s):

MQP	SUSTAIN® R TPS Spacers (Cervical & Lumbar)
	FORTIFY®-R TPS Corpectomy Spacer
	FORTIFY® I-R TPS Corpectomy Spacer
	XPand®-R TPS Corpectomy Spacer
	NIKO® TPS Corpectomy Spacer
MAX	SUSTAIN® R TPS Spacers (Lumbar)
	PATRIOT® TPS Spacers (Lumbar)
	CALIBER® TPS Spacer
ODP	SUSTAIN® R TPS Spacers (Cervical)
	PATRIOT® TPS Spacers (Cervical)
	COALITION® TPS Spacers
OVE	COALITION® TPS Spacers
OVD	INDEPENDENCE® TPS Spacer

Regulatory Class: II, Panel Code: 87

Primary Predicate: Aurora Spine Interbody Fusion System (K133967)

Additional Predicates:

SUSTAIN® R Spacers (K040284 & K130478)
PATRIOT® Spacers (Cervical) (K072991)
PATRIOT® Spacers (Lumbar) (K072970 & K122097)
PATRIOT® TransContinental® Spacer (K093242)
PATRIOT® TransContinental® M Spacer (K102313)
CALIBER® Spacer (K102293 & K123231)
COALITION® Spacer (K083389 & K131449)
INDEPENDENCE® Spacer (K082252 & K120101)
FORTIFY®-R Corpectomy Spacer (K112756)
FORTIFY® I-R Corpectomy Spacer (K121107)
XPand®-R Corpectomy Spacer (K060665)
NIKO® Corpectomy Spacer (K072465)

Purpose:

The purpose of this submission is to request clearance of the following titanium plasma spray coated PEEK spacers: SUSTAIN® R TPS Spacers, PATRIOT® TPS Spacers, CALIBER® TPS Spacer, COALITION® TPS Spacers, INDEPENDENCE® TPS Spacer, FORTIFY®-R TPS Corpectomy Spacer, FORTIFY® I-R Corpectomy TPS Spacer, XPand®-R TPS Corpectomy Spacer, and NIKO® TPS Corpectomy Spacer.

Device Description:

SUSTAIN® Spacers

SUSTAIN® Spacers (including SUSTAIN® R and SUSTAIN® R TPS) are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. These spacers are available in different shapes and heights to accommodate various surgical approaches and anatomical needs. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

These spacers are used to provide structural stability in skeletally mature individuals following discectomy, corpectomy, or vertebrectomy (including partial). Lumbar spacers may be inserted using a posterior, transforaminal, anterior, anterolateral, or lateral lumbar approach. Cervical spacers are inserted using an anterior cervical approach.

The SUSTAIN® Spacers are made from commercially pure titanium or titanium alloy as specified in ASTM F67, F136, and F1295. SUSTAIN® Radiolucent (SUSTAIN® R) and SUSTAIN® R TPS Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026. SUSTAIN® R TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

PATRIOT® Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Constitution® TPS, Signature®, Signature® TPS, Continental®, Continental® TPS, TransContinental®, TransContinental® TPS, TransContinental® M and TransContinental® M TPS) are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. Each of the PATRIOT® spacers provides a different shape to accommodate various surgical approaches to the lumbar spine. Constitution® PLIF Spacers are inserted using a posterior approach. Signature® TLIF Spacers are inserted using a transforaminal approach. Continental® ALIF Spacers are inserted using an anterior approach. Transcontinental® and TransContinental® M Spacers are inserted using an anterior or lateral approach. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

PATRIOT® Spacers are made from PEEK radiolucent polymer (ASTM F2026) with titanium alloy or tantalum markers (ASTM F560). Signature® R Spacers also include an internal titanium alloy or commercially pure titanium (ASTM F67) component, and TransContinental® M Spacers also include an integrated titanium alloy nut. The Signature® Ti Spacer is made from titanium alloy or commercially pure titanium. The titanium alloy is TAV (ASTM F136) or TAN (ASTM F1295). PATRIOT® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

PATRIOT® Cervical Spacers

PATRIOT® Spacers (including COLONIAL® and COLONIAL® TPS) are cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. COLONIAL® ACDF Spacers are inserted through an anterior cervical approach, and are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

PATRIOT® Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in F2026, F136, F1295, and F560. PATRIOT® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

CALIBER® Spacers

CALIBER® Spacers (including CALIBER® TPS) are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. CALIBER® Spacers provide different shapes to accommodate various surgical approaches to the lumbar spine (posterior,

transforaminal [posterolateral] or lateral). The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

CALIBER® Spacers are manufactured from radiolucent PEEK polymer and titanium alloy per ASTM F2026, F136 and F1295; non-expandable CALIBER® Spacers are manufactured from PEEK only. CALIBER® Spacers contain radiopaque titanium alloy or tantalum markers as specified in ASTM F136, F1295 and F560. CALIBER® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

COALITION® Spacers

COALITION® Spacers (including COALITION® TPS) are stand-alone cervical interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. COALITION® Spacers are inserted through an anterior cervical approach, and are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacers are to be filled with autogenous bone graft material.

COALITION® Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. The anterior portion of the implant and the mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295. COALITION® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDEPENDENCE® Spacers

INDEPENDENCE® Spacers (including INDEPENDENCE® TPS) are stand-alone anterior lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacers are to be filled with autogenous bone graft material.

INDEPENDENCE® Spacers are made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. The anterior portion of the implant and the mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The screws are available

with or without hydroxyapatite (HA) coating, as specified in ASTM F1185. INDEPENDENCE® TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

FORTIFY® Corpectomy Spacers

FORTIFY® (including FORTIFY®-R and FORTIFY®-R TPS) and FORTIFY® Integrated (including FORTIFY® I-R and FORTIFY® I-R TPS) Corpectomy Spacers are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The components include a central core and endplates, which are available in a range of sizes and options to accommodate the anatomical needs of a wide variety of patients. The core and endplates can be preoperatively or intraoperatively assembled to best fit individual requirements. Each spacer has an axial hole to allow autogenous bone graft or allograft to be packed inside the spacer. Protrusions (teeth) on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Additional spikes are available on some implants. FORTIFY® Integrated endplates have an integrated plate to accommodate screws for additional fixation and are assembled to the core.

FORTIFY® and FORTIFY® I-R Corpectomy Spacers are manufactured from titanium alloy per ASTM F136 and F1295. FORTIFY®-R, FORTIFY®-R TPS, FORTIFY® I-R, and FORTIFY® I-R TPS Corpectomy Spacers are manufactured from radiolucent PEEK polymer, with titanium alloy and tantalum components, per ASTM F2026, F136, F1295, and F560. Screws are manufactured from titanium alloy per ASTM F136 and F1295, with or without hydroxyapatite coating per ASTM F1185. FORTIFY® R TPS and FORTIFY® I-R TPS Corpectomy Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

XPand® Corpectomy Spacers

XPand® Corpectomy Spacers (including XPand®-R and XPand®-R TPS) are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various heights and footprints to fit the anatomical needs of a wide variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside the spacer. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

The XPand® devices are made from titanium alloy as specified in F136 and F1295. The XPand®-R and XPand®-R TPS Corpectomy Spacers are made from radiolucent polymer and titanium alloy as specified in ASTM F2026, F136 and F1295, and include markers made from titanium alloy or tantalum as specified in ASTM F136, F1295 and F560. XPand®-R TPS Corpectomy Spacers also have a

commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

NIKO® Corpectomy Spacers

NIKO® Corpectomy Spacers (including NIKO® TPS) are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various fixed heights to fit the anatomical needs of a variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside the spacer. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

NIKO® Corpectomy Spacers are made from radiolucent polymer and titanium alloy or tantalum as specified in ASTM F2026, F136, F1295, and F560. NIKO® TPS Corpectomy Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

Indications for Use:

SUSTAIN® Spacers

When used as lumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R and SUSTAIN® R TPS) are intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). SUSTAIN® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE®, REVOLVE®, or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. SUSTAIN® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE®, or XTEND® Anterior Cervical Plate Systems.

When used as vertebral body replacement devices, SUSTAIN® Spacers are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior

pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with bone grafting material. SUSTAIN® Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

PATRIOT® Lumbar Spacers

PATRIOT® Spacers (including Constitution®, Constitution® TPS, Signature®, Signature® TPS, Continental®, Continental® TPS, TransContinental®, TransContinental® TPS, TransContinental® M, and TransContinental® M TPS) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

PATRIOT® Cervical Spacers

PATRIOT® Spacers (including COLONIAL® and COLONIAL® TPS) are interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc as confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment.

PATRIOT® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the ASSURE® or PROVIDENCE® Anterior Cervical Plate Systems.

CALIBER® Spacers

CALIBER® Spacers (including CALIBER® TPS) are interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

CALIBER® Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE® or REVOLVE® Stabilization Systems.

COALITION® Spacers

COALITION® Spacers (including COALITION® TPS) are stand-alone interbody fusion devices intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. COALITION® Spacers are to be filled with autogenous bone graft material, and are to be used with two titanium alloy screws which accompany the implants.

INDEPENDENCE® Spacers

INDEPENDENCE® Spacers (including INDEPENDENCE® TPS) are stand-alone interbody fusion devices intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). INDEPENDENCE® Spacers are to be filled with autogenous bone graft material, and are to be used with three titanium alloy screws, which accompany the implants.

FORTIFY® Corpectomy Spacers

FORTIFY® (including FORTIFY®-R and FORTIFY®-R TPS) and FORTIFY® Integrated (including FORTIFY® I-R and FORTIFY® I-R TPS) Corpectomy Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These devices are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with autogenous bone graft or allograft. These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

XPand® Corpectomy Spacers

XPand® Corpectomy Spacers (including XPand®-R and XPand®-R TPS) are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). XPand® Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate system, and anterior screw and rod systems). The interior of the spacer can be packed with bone grafting material. XPand® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

NIKO® Corpectomy Spacers

NIKO® Corpectomy Spacers (including NIKO® TPS) are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). NIKO® Corpectomy Spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with bone grafting material. NIKO® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.

Performance Data:

Performance of TPS Spacers was evaluated in accordance with the "Guidance for Industry and FDA Staff, Class II Special Controls Guidance Document: Intervertebral Fusion Device," June 12, 2007. Dynamic compression shear and dynamic torsion testing was performed per ASTM F2077.

Coating characterization testing was conducted in accordance with the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements," February 2, 2000, and ASTM F1044, F1147, F1160, F1854, and F1978, with additional wear analysis to demonstrate adequate coating of the implants.

Basis of Substantial Equivalence:

TPS Spacers have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. TPS Spacers are as safe, as effective, and perform as well as or better than the predicate devices.